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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,360

03/19/2004

Roger Farnholtz

1001.1690102

9216

28075 7590 11/12/2009
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EXAMINER

BERDICHEVSKY, AARTI

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,360	Applicant(s) FARNHOLTZ, ROGER	
	Examiner Aarti Bhatia Berdichevsky	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22,24-26,28-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22,24-26,28-35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the sixth Office Action based on the 10/804,360 application filed on 3/19/2004.

Claims 19-22, 24-26, 28-35, and 37-38, as amended on 9/21/2009, are currently pending and have been considered below.

Response to Amendment

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the distal end (and the proximal end) of the tubular shaft must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19-22, 24-26, 28-35 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The claims recite a polymer layer, which is disposed both under and over the braid. It is unclear whether there is a single polymer coating that covers both the braid and the nitinol tubing, or whether there are two separate coatings, which are distinct from each other. The braid is described in the specification to be embedded in a layer of hydrophobic polymer (page 4, lines 10-13), however from the claims and the drawings, the braid does not appear to be embedded in either layer. Furthermore, the claims recite “a braid attached to the distal end of the tubular shaft”, which in the specification is described as junction 186 (page 5 lines 15-17). This junction is shown inconsistently between figures 2A and 2B. In figure 2A, it appears that braid 170 is

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distal of junction 186, whereas in figure 2B, it appears that braid 170 is both distal and proximal of junction 186. It is unclear in what manner braid 170 is "attached" to the tubular shaft. The distal end of tube 182 is not clearly defined in the specification (or the drawings), therefore it is unclear from the claims whether tube 182 has its distal end near junction 186, or whether it extends all the way to the distal end (which is also not defined) of distal tip 50. The Examiner is examining the claims as if there is simply some level of overlap between the tubular member and the braided member.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 19, 20, 21, 22, 24, 26, 28, 29, 30, 31, 32, 33, 35, 37, and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,228,441 to Lundquist in view of USPN 5,057,092 to Webster, Jr. in further view of USPN 5,702,373 to Samson.

Lundquist teaches the torqueable and deflectable medical device shaft as generally claimed (see previous office action) but fails to teach that the braided portion should extend to the distal end of the distal shaft portion and is embedded between two polymer layers over the tubular layer.

Webster teaches a catheter with a braided layer (24) that extends to the distal end, and is disposed over a polymer layer (22) and that has a outer polymer layer (30) covering the tubular shaft and the braid.

Samson teaches a similar catheter where the braided layer overlies the distal end of a metallic tubular member (see figure 11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the torqueable and deflectable catheter of Lundquist with the polymer layers of Webster and Samson to produce a catheter section that is very flexible but highly kink resistant (Samson, abstract).

7. Claims 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist, Webster Jr, and Samson in further view of U.S. Patent No. 5,437,288 to Schwartz.

Lundquist, Webster Jr, and Samson make obvious the medical device of claims 19 and 28, and Lundquist teaches that there can be variation in the number, frequency, and location of slits (column 4, lines 20-37) but fails to disclose wherein the depth of slits is greater near the distal end/junction of the proximal shaft section than near the proximal end/junction of the proximal shaft section.

Schwartz teaches a flexible catheter (figure 2), where the depth of slits (14) becomes greater when moving from the proximal end (11) to the distal end (12) (column 4, lines 5-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the flexible catheter made obvious by Lundquist, Webster Jr, and Samson with the variable depth slits of Schwartz because by increasing the depth of the grooves, the flexibility of the flexible portion nearest the distal end is increased (column 4, lines 8-11).

Response to Arguments

8. Applicant's arguments filed 9/21/2009 have been considered but are moot in view of the new ground(s) of rejection based on the newly amended claims presented by applicant.
9. The Examiner withdraws the previous objection made on 11/21/2009 to the drawings, but finds that the drawings (and the specification) are inconsistent with the current claim limitations (see objection to drawings and 112 rejections above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia Berdichevsky whose telephone number is 571-270-5033. The examiner can normally be reached M-Th 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia Berdichevsky/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763